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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,640	11/28/2001	Jianwu Dai	TSS-052CP	5695

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EXAMINER

NAFF, DAVID M

ART UNIT PAPER NUMBER

1651

DATE MAILED: 01/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/996,640

Applicant(s)

DAI ET AL

Examiner

David M. Naff

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 32-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 32-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

Art Unit: 1651

The amendment of 9/24/03 amended claims 1 and 5-20, canceled claims 21-31 and added new claims 32-36.

Claims examined on the merits are 1-20 and 32-36 which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

Claims 5-13, 16-20 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1651

To be consistent and clear, claims 5, 7-13, and 17-20 should be amended to recite "produced as is" after "material" in line 1 as recited in claims 14-16. In line 2 of claims 5 and 20, --- as --- should be inserted before "in", and in line 1 of claims 7-10 and 17-19 and line 2 of claims 11-13, --- produced -- should be inserted before "as".

Claim 6 is unclear by reciting "with with" (bridging lines 1 and 2 of step f. Additionally, in line 2 of the step, a comma should be inserted after "complexes" and the comma after "cells" should be deleted, and in line 3 of the step "with" should be deleted.

In line 2 of step f of claim 6, the term "signaling complexes" is uncertain as to meaning and scope. This does not appear to be an art recognized term, and it is not defined in the specification.

Claim 16 is unclear by depending on claim 5 and in line 3 reciting "to repair or replace a rotator cuff" which is not consistent with soft tissue augmentation as required in line 2, and which is already required in line 3 of claim 12. Claim 5 is drawn to a method of using the scaffold material and not to a method of producing the scaffold material.

Claim 36 is unclear in line 3 as to the material treated with sodium hydroxide, and when in the method this treatment is

Art Unit: 1651

carried out. Is the sodium hydroxide used for treatment after the scaffold material is combined with growth and differentiation factors, or is the sodium hydroxide used in extracting the growth and differentiation factors? It is unclear where the specification describes using sodium hydroxide as required in claim 36.

***Claim Rejections - 35 USC § 103***

Claims 1-20 and 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brendel et al (4,801,299) in view of Bell et al (6,179,872 B1) and Evans et al (5,989,431) (newly applied), and if necessary in further view of Berlowitz-Tarrant et al (5,779,960) (newly applied).

The claims are drawn to a method of producing a biopolymer scaffold by harvesting tissue, inactivating infective agents, applying pressure to remove undesirable components, delipidizing and washing, and to methods of using the scaffold.

Brendel et al disclose (col 2, line 48 to col 3, line 58) producing an extracellular matrix for implanting by treating tissue to remove cellular membranes, nucleic acids, lipids and cytoplasmic components by treating tissue with detergents, washing, treating with ethylene oxide or irradiation to sterilize, and lyophilizing. Crosslinking may also be performed.

Art Unit: 1651

Bell et al disclose (col 1, lines 46-57) producing extracellular matrix particulates from tissue for use in preparing a biopolymer matt for repairing tissue. Tissue is processed by grinding, washing and sieving to remove cytoplasmic and nuclear components , and the resultant extracellular matrix is freeze-dried. When a fibril solution is applied to a filter (col 9, lines 35-37), solution flow through the filter may be assisted by applying a negative pressure to the opposite side of the filter (col 9, lines 46-48).

Evans et al disclose (col 4, lines 27-31) washing cells on a filter by passing a wash solution through the filter under positive or negative pressure.

Berlowitz-Tarrant et al disclose (col 14, lines 18-22), after harvesting algae, mechanically expressing water by using pressure.

When carrying out washing in the process of Brendel et al, it would have been obvious to place the extracellular matrix on a filter and pass water through the filter as suggested by Bell et al and Evans et al, and it would have been obvious to apply a positive or negative pressure to the filter to assist the flow of water through the extracellular matrix on the filter as suggested by Bell et al and Evans et al, and if needed as further suggested by Berlowitz-Tarrant et al to remove wash

Art Unit: 1651

water from the extracellular matrix. Washing will inherently remove undesirable components. The use of detergents, washing with a solution of ethanol and storing in ethanol (col 5, lines 62-66) as disclosed by Brendel et al would have resulted in inactivating infective agents and delipidizing as claimed. The conditions of dependent claims would have been matters of obvious choice in view of the disclosures of the references. The uses disclosed by Brendel et al (col 4, lines 31-64) and by Bell et al (col 16, lines 30-50) would have suggested the uses required by dependent claims. Combining with stem cells or growth and differentiation factors would have been obvious to hasten the formation of new tissue. The use of sodium hydroxide as in claim 36 would have been obvious since sodium hydroxide is a well known hydrolysis agent. A blood vessel as in claim 32 would have been suggested by Brendel et al disclosing carotid arteries (col 3, line 15).

#### ***Response to Arguments***

Applicants urge that Bell et al cannot be properly applied under 35 U.S.C. 103 under 102(e) because of common assignment. However, Bell et al is not applied under 102(e) since Bell et al was published 1/30/01 which is before the filing date of 5/31/01 of parent application 09/871,518.

Art Unit: 1651

Applicants additionally urge that applying pressure to remove undesirable components is unobvious. However, in view of Bell et al and Evans et al, and if needed Berlowitz-Tarrant et al, applying pressure during washing would have been obvious, and washing will remove undesirable components.

### ***Double Patenting***

Claims 1-20 and 32-36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-46 of copending Application No. 09/871,518. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims encompass the methods of producing a biopolymer scaffold claimed by the copending application, and would have been obvious therefrom.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

Applicants indicate that a terminal disclaimer will be filed when allowable claims are found.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is

Art Unit: 1651

reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 703-308-0520. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1651

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'DMN', with a large, stylized flourish extending from the end.

David M. Naff  
Primary Examiner  
Art Unit 1651

DMN

12/24/03